Irish Blood Transfusion Service
Seirbhís Fuilaistriúcháin na hÉireann

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Level	Owner Role	Actor	Sign-off By
1	DIAGNOSTICS WRITER NBC	MARY KEENAN	MARY KEENAN
1	DIAGNOSTICS WRITER MRTC	ORLA CROWLEY	ORLA CROWLEY
2	QUALITY ASSURANCE REVIEWER NBC	MARGARET KAVANAGH	MARIE O'CONNELL
2	QUALITY ASSURANCE REVIEWER MRTC	COLIN JOHNS	COLIN JOHNS
2	MEDICAL HEAD OF DEPT NBC	WILLIAM MURPHY	WILLIAM MURPHY
2	DIAGNOSTICS HEAD OF DEPT MRTC	KEVIN SHEEHAN	KEVIN SHEEHAN
2	MEDICAL HEAD OF DEPT MRTC	JOAN POWER	SMARTCOMM
2	MEDICAL HEAD OF DEPT MRTC	JOAN POWER	MARIE O'CONNELL
2	MEDICAL HEAD OF DEPT MRTC	WILLIAM MURPHY	REBECCA WALDEN
2	DIAGNOSTICS HEAD OF DEPT NBC	JOHN CRUMLISH	JOHN CRUMLISH

Change Orders

Changes as described on Change Order: **Change Order No.**

Change Orders - Incorporated

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BT No.: 0425	Ver. 4
IRISH BLOOD TRANSFUSION SERVICE	

TITLE: TRACEABILITY USER MANUAL

Supersedes Version: 3

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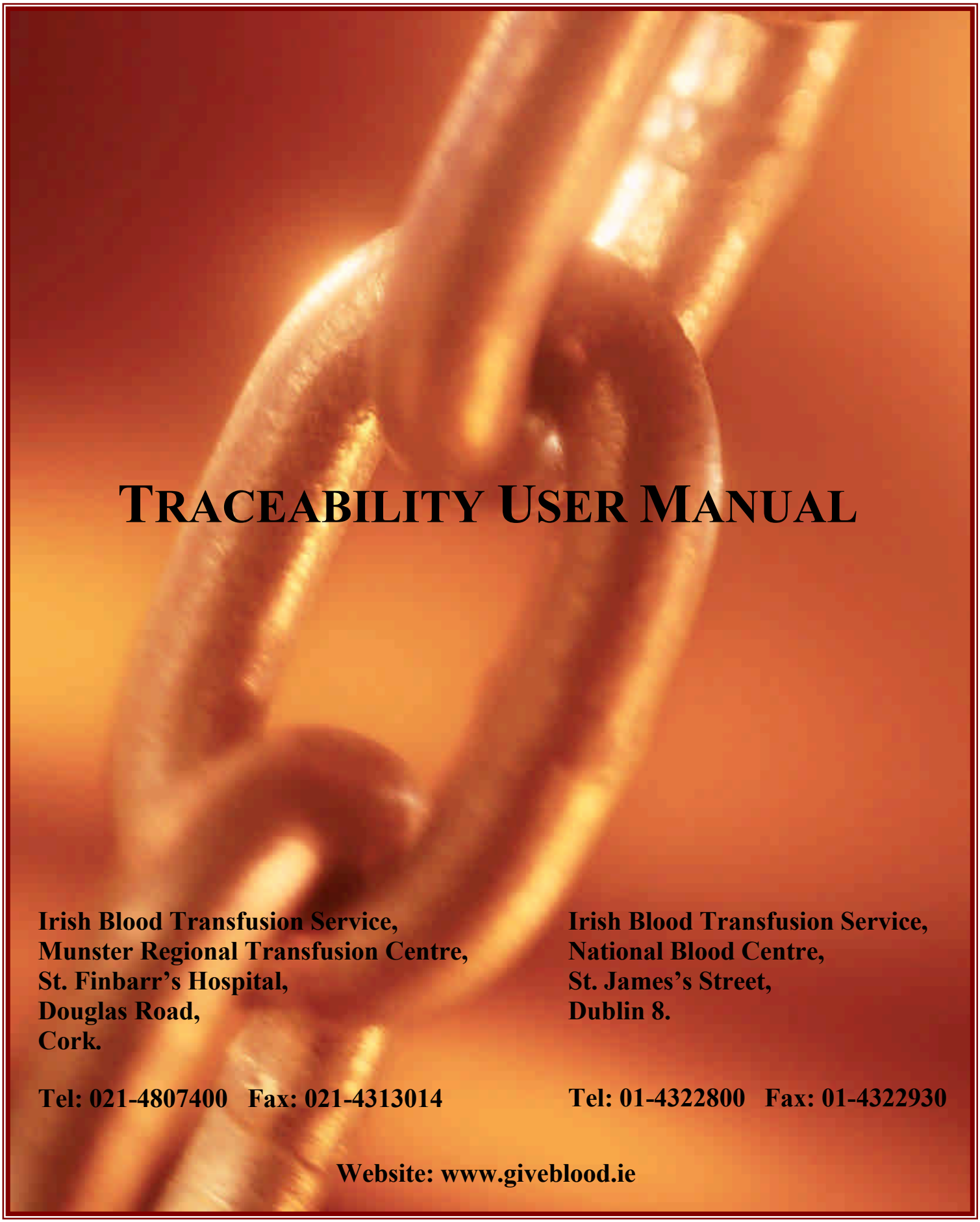
This BT form may be printed directly from EQMS/Internet for use.



TRACEABILITY USER MANUAL

Irish Blood Transfusion Service,
Munster Regional Transfusion Centre,
St. Finbarr's Hospital,
Douglas Road,
Cork.

Tel: 021-4807400 Fax: 021-4313014

Irish Blood Transfusion Service,
National Blood Centre,
St. James's Street,
Dublin 8.

Tel: 01-4322800 Fax: 01-4322930

Website: www.giveblood.ie

BT 425-4 June 2014

INDEX

*** This service issue applies to the Munster Region only**

1. Introduction

1.1 SI 547 of 2006 requires that the IBTS, where it acts as a Hospital Blood Bank, has a system in place to trace the final fate of each and every unit of blood component supplied (100%). This statutory instrument requires that, inter alia, **(Regulation 4)** "each blood establishment, hospital blood bank and facility shall ensure the compatibility traceability of blood/ blood components with accurate identification procedure, record maintenance and appropriate labelling".
(Regulation 7) "each blood bank should have a system in place for each blood unit or blood component received whether or not locally processed and the final destination of that unit whether transfused, discarded or returned to the distributing blood establishment …"
And - in relation to verification –
(Regulation 9) "each blood establishment/ blood bank must have in place a procedure, when it issues units of blood or blood components for transfusion to verify that each unit issued has been transfused to the intended recipient or if not transfused to verify subsequent disposition"
And
(Regulation 10) "each blood establishment/ hospital blood bank and facility shall retain the data set in the first schedule here to for at least 30 years in an appropriate readable storage medium in order to ensure compatibility traceability."
Where the first schedule sets out requirement for facilities as
blood component supplier/ unit identification or lot number/ transfusion recipient identification/ date of transfusion or disposition/ and for blood units not transfused confirmation of subsequent disposition.

1.2 The IBTS Diagnostic services will comply by use of the 'Bag & Tag' compatibility traceability system. This involves the tagging of a compatibility/ traceability label (BT 396) to the component and the subsequent manual entry of the date of transfusion together with the confirmation of transfusion (or any part thereof) recipient identification or other disposition (other patient/ transferred/ re routed/ discarded) on the eTraceline patient record from the information returned (part C of BT 396) from the user hospital **and** the retention of a hard copy of part C of BT 396 for 30 years.

1.3 The Traceability Programme was implemented to fulfil the requirements of *SI 547 of 2006 European Community (Human Blood and Blood Components Traceability Requirements and Notification of Serious Adverse Reactions and Events) Regulations 2006.*
The regulations require unambiguous traceability of all blood and blood components from donor to patient and documentation of final fate if not transfused.

1.4 The intent is to identify all transfusion linked donors and patient therefore where a patient is exposed to **any** portion of a donor's blood component this link must be identified. This includes where a few mls is transfused or indeed where the line has tissued.

1.5 The Compatibility/ Traceability Label (BT 396) will be issued with all blood and blood components from the IBTS to patients in facilities where the IBTS acts as their blood bank in the provision of a routine compatibility service. Return of the Compatibility/ Traceability Label (BT 396) allows unambiguous traceability and the final fate of the blood component.

1.6 It is the responsibility of the Haemovigilance Officer/Nominee to ensure the prompt return of fully completed section C (blue) of the compatibility/ traceability labels.

2. Compatibility/ Traceability Label (BT 396)

A Compatibility/ Traceability Label (BT 396) is issued with all* blood and blood components from the IBTS to patients in facilities where the IBTS acts as their blood bank in the provision of a routine compatibility service.
* For exceptions to this see Section 4.5

Components include

(i) Red Cell Preparations

(ii) Platelets

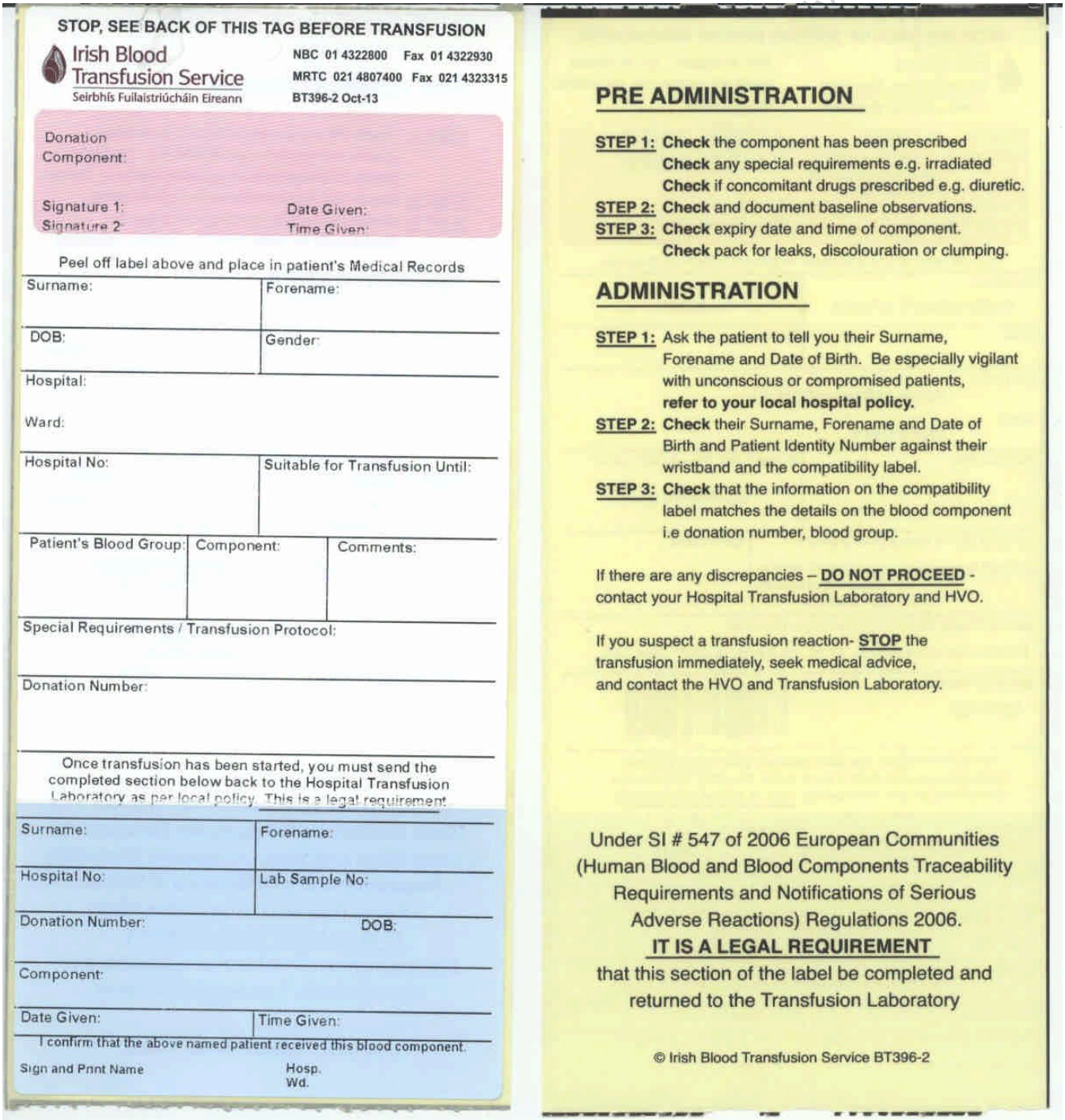
(iii) Plasma Components inc. Fresh Frozen Plasma and Cryoprecipitate (Solvent Detergent (SD) plasma is not within the scope of the regulation)

Care should be exercised when handling the unit to ensure that the label is not detached from the unit.

In the unlikely event that the label becomes detached from the unit, it should not be transfused.
The Crossmatch Laboratory should be advised and the unit returned.

2. Compatibility/ Traceability Label (BT 396)

The compatibility/ traceability label (BT 396) holds service related information on the face and instructions on the back as below



STOP, SEE BACK OF THIS TAG BEFORE TRANSFUSION

Irish Blood Transfusion Service
Seirbhís Fuilaistriúcháin Eireann

NBC 01 4322800 Fax 01 4322930
MRTC 021 4807400 Fax 021 4323315
BT396-2 Oct-13

Donation Component:

Signature 1:
Signature 2:

Date Given:
Time Given:

Peel off label above and place in patient's Medical Records

Surname: | Forename:

DOB: | Gender:

Hospital:

Ward:

Hospital No: | Suitable for Transfusion Until:

Patient's Blood Group: | Component: | Comments:

Special Requirements / Transfusion Protocol:

Donation Number:

Once transfusion has been started, you must send the completed section below back to the Hospital Transfusion Laboratory as per local policy. This is a legal requirement

Surname: | Forename:

Hospital No: | Lab Sample No:

Donation Number: DOB:

Component:

Date Given: | Time Given:

I confirm that the above named patient received this blood component.

Sign and Print Name Hosp. Wd.

PRE ADMINISTRATION

STEP 1: **Check** the component has been prescribed
Check any special requirements e.g. irradiated
Check if concomitant drugs prescribed e.g. diuretic.
STEP 2: **Check** and document baseline observations.
STEP 3: **Check** expiry date and time of component.
Check pack for leaks, discolouration or clumping.

ADMINISTRATION

STEP 1: Ask the patient to tell you their Surname, Forename and Date of Birth. Be especially vigilant with unconscious or compromised patients, **refer to your local hospital policy.**
STEP 2: **Check** their Surname, Forename and Date of Birth and Patient Identity Number against their wristband and the compatibility label.
STEP 3: **Check** that the information on the compatibility label matches the details on the blood component i.e donation number, blood group.

If there are any discrepancies – **DO NOT PROCEED** - contact your Hospital Transfusion Laboratory and HVO.

If you suspect a transfusion reaction- **STOP** the transfusion immediately, seek medical advice, and contact the HVO and Transfusion Laboratory.

Under SI # 547 of 2006 European Communities (Human Blood and Blood Components Traceability Requirements and Notifications of Serious Adverse Reactions) Regulations 2006.
IT IS A LEGAL REQUIREMENT
that this section of the label be completed and returned to the Transfusion Laboratory

The information will be printed by the laboratory
(or handwritten in the event of a technology failure)

3. Ties

The Compatibility/ Traceability Label (BT 396) is attached to the pack by way of a plastic tie (as shown).

This should be received in your hospital with the tie uppermost (as shown below) at the open end of the overwrap and stored in this position.

This is to prevent the tie causing a pack tear from pressure on the pack.

4. Management of Compatibility/ Traceability Label (BT 396)

4.1 Overview

The Crossmatch Laboratory may issue components:-

- To assigned patients – this may be transfused to the intended or an unintended recipient.
  Such components could be transferred with a patient to another facility and within Cork City such components could be rerouted to CUH.

- Labelled as emergency stock to be held on hospital site (non-assigned).
  Such components could be transferred with a patient to another facility and within Cork City such components could be rerouted to CUH.

- Unlabelled in case of life threatening emergency.

The following section details the appropriate management for each circumstance.

4.2 Management of BT 396 - Assigned Patient

1. Hospital procedures cover the issue of components for transfusion and management in the clinical area.

2. On completion of independent identification checks and pack inspection as per hospital procedure, Practitioner (1) and Practitioner (2) sign the Pink Section of the Compatibility/ Traceability Label (BT 396) before commencing the transfusion.

   Space is limited on the blue section of the Traceability Label. Where a patient has lengthy forenames, first and second forenames will be printed, but a third is unlikely to be. The complete name is present on the 6000 Report.

3. Once the transfusion has commenced, the completed "peel off" pink portion of the Compatibility/ Traceability Label (signed by both practitioners) is attached to the relevant place in the patient's medical notes.

4. Once the transfusion is under-way, the practitioner signs the Blue Section (c) of the Compatibility/ Traceability Label. The time given should be documented using the 24 hour time format with day ending at 23:59 and new day commencing at 00:00. This section must be returned to the Crossmatch Laboratory as per the procedures in hospitals for which the IBTS acts as a blood bank.
   (Remember the donor-patient link must be made once the transfusion has **commenced**)

5. The White Section of the Compatibility/ Traceability Label should be retained with the component until disposal of the pack. In the event of a patient adverse event the laboratory require this for pack inspection verification.

4.3 Blood Component Which was <u>not</u> Transfused to the Patient for Whom it was Originally Labelled, but Transfused to a Different Patient

On completion of pack inspection as per hospital procedure, prior to commencing transfusion Practitioner (1) and Practitioner (2) sign the Pink Section of the Compatibility/ Traceability Label (BT 396).

Once transfusion has commenced the Pink Section should be retained in the patient's chart, as per hospital procedure.

Where a blood component not transfused to the patient for whom it was originally labelled was transfused to a different patient,
The *Traceability Form for Transfusion Confirmation of Non-Assigned Blood Components* (IBTS/DIAG/SOP/0030 Att. 6.1) should be completed with

(1) The patient details of the patient to whom the blood component was transfused
(2) Transfusion details
(3) Confirmation of transfusion

The Blue Section (c) of the Compatibility/ Traceability Label (BT 396) should be affixed to the designated area.
NB No patient, practitioner details, date or signature should be completed in the blue section.

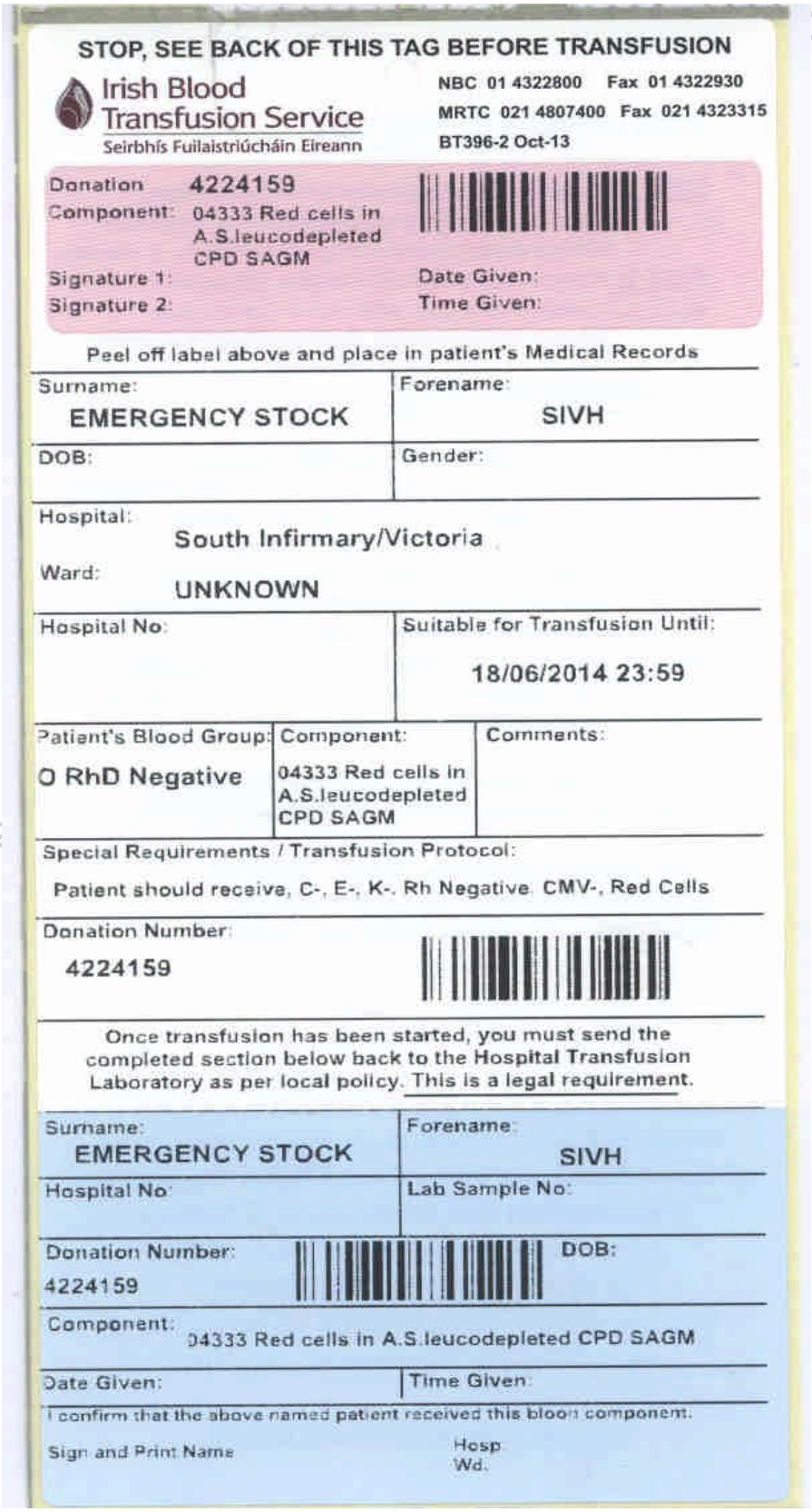
If the staff member completing the Traceability Form was not a witness to transfusion, then prior to completing the Traceability Form, she/he must have reviewed the patient's chart to confirm transfusion to the named patient.

IBTS/DIAG/SOP/0030 Att. 6.1.

This service issue applies to the Munster Region only

4.4. Blood Component Issued Labelled as Emergency Stock (non-assigned Blood Component)

4.4.1 Compatibility/ Traceability Label BT 396 labelled as emergency stock



STOP, SEE BACK OF THIS TAG BEFORE TRANSFUSION

Irish Blood Transfusion Service
Seirbhís Fuilaistriúcháin Eireann

NBC 01 4322800 Fax 01 4322930
MRTC 021 4807400 Fax 021 4323315
BT396-2 Oct-13

Donation 4224159
Component: 04333 Red cells in A.S.leucodepleted CPD SAGM
Signature 1:
Signature 2:
Date Given:
Time Given:

Peel off label above and place in patient's Medical Records

Surname: EMERGENCY STOCK	Forename: SIVH
DOB:	Gender:

Hospital: South Infirmary/Victoria
Ward: UNKNOWN

Hospital No:	Suitable for Transfusion Until: 18/06/2014 23:59

Patient's Blood Group:	Component:	Comments:
O RhD Negative	04333 Red cells in A.S.leucodepleted CPD SAGM	

Special Requirements / Transfusion Protocol:
Patient should receive, C-, E-, K-, Rh Negative. CMV-, Red Cells

Donation Number: 4224159

Once transfusion has been started, you must send the completed section below back to the Hospital Transfusion Laboratory as per local policy. This is a legal requirement.

Surname: EMERGENCY STOCK	Forename: SIVH
Hospital No:	Lab Sample No:
Donation Number: 4224159	DOB:

Component: 04333 Red cells in A.S.leucodepleted CPD SAGM

Date Given:	Time Given:

I confirm that the above named patient received this blood component.

Sign and Print Name
Hosp
Wd.

4.4.2 Blood Component Issued Labelled as Emergency Stock Which has Been Transfused to a Patient

On completion of pack inspection as per hospital procedure, prior to commencing transfusion, Practitioner (1) and Practitioner (2) sign the pink section of the compatibility traceability label.

Once the transfusion has commenced the pink section should be retained in the patient's chart as per hospital procedure.

The hospital returning the Compatibility/ Traceability Label will fill out a *Traceability Form for Transfusion Confirmation of Non-Assigned Blood Components*
IBTS/DIAG/SOP/0030 (Att 6.1) containing the patient details of the patient to whom the blood component was transfused, transfusion details, and confirmation of transfusion.

The Traceability Form for Transfusion Confirmation of Non-Assigned Blood Components will be returned to the IBTS with the Blue Section of the Compatibility Traceability Label (BT 396) affixed to the designated section.

No patient, practitioner details, date or signature should be completed on the Blue Section.

If the staff member completing the Compatibility Traceability Form was not a witness to transfusion, then prior to completing the Compatibility Traceability Form, she/he must have reviewed the patient chart to confirm transfusion to the named patient.

4.5 Unlabelled Blood Component Issued in an Emergency

Red cell components of group O Rh D negative (Emergency Stock) may be issued in acute life threatening situations. In such emergencies these units will be issued as emergency stock with traceability label on them. Serological tests will not have been performed on these units prior to issue but will be done retrospectively.

4.6 Inter Hospital Transfer of Patient with Assigned Blood Components

Transfusion Commenced Prior to Transfer

Where transfusion is commenced prior to transfer, management should be as for an assigned patient, with Part C of the Compatibility/ Traceability Label (BT 396) returned to the Crossmatch Laboratory by the hospital from which the patient is being transferred. The Pink Section is to be completed and inserted in the hospital chart.

Transfusion during Inter-Hospital Transfer

Where a patient is transferred to another hospital with components, the Compatibility/ Traceability label (BT 396) is retained with the component on transfer.

Where transfusion is required for the patient in transit the RGN/MO accompanying the patient should complete the Pink Section and insert it in the hospital chart.

The Blue Section (c) should be completed and returned to the HVO in the hospital from which the patient was transferred by the RGN accompanying the patient.

Where transfusion is required for the patient in the receiving hospital prior to transfused units being entered into hospital inventory (stock), the RGN/MO accompanying the patient should complete the Pink Section and insert it in the hospital chart.

The Blue Section (c) should be completed and returned to the HVO in the hospital from which the patient was transferred by the RGN accompanying the patient to be sent on by the HVO to the Blood Bank from which the unit was issued / crossmatched.

Transfusion Post Hospital Transfer

On admission to the receiving hospital, where transferred units are entered into Hospital inventory (Stock) and managed as per hospital practice, traceability is the responsibility of the receiving hospital Blood Bank.
Confirmation of receipt of such components into hospital inventory should be sent to the relevant IBTS compatibility laboratory.

This service issue applies to the Munster Region only

4.7 Rerouted Blood Components

Where a red cell component is rerouted to CUH from a MRTC crossmatch facility under the approved re routing/ red cell optimisation scheme, the BT 396 should be retained with the component on transfer.
CUH will confirm receipt of such components into CUH Hospital inventory and CUH will return the BT 396 directly to the compatibility laboratory at the Munster Regional Transfusion Centre.

This service issue applies to the Munster Region only

4.8 Unused Blood Components

Where a blood component is issued from the IBTS blood bank with the traceability label attached, **BUT** is not transfused/ used etc, this should be returned to MRTC or the Dublin Centre Laboratory with the tag attached to ensure appropriate fating. This applies to red cells, platelets, fresh frozen (not solvent detergent) plasma and cryoprecipitate.

5. Records – How to Write and Correct Your Data

Records are detailed, written accounts of an operation. We are required by our quality system to keep accurate records of all our activities. We consider this to be a very important part of our practice.

If the records are not correct, we cannot guarantee that the fating is correct!!!

There are forms provided for most activities. These will ensure that you record all relevant information. It is important that these forms are filled in correctly and accurately.

Black indelible pen should be used for all written records and forms. Pencil is not acceptable.

Handwriting should be neat and clear.

Information should be recorded such that it could be read and understood by someone less familiar with the operation.

Care should be taken not to make mistakes when recording information. However, if you do make a mistake, it should be corrected as follows:

- A single line should be marked through the incorrect information. This cross out should not make the initial information illegible, e.g., ~~mistake.~~
- The correct information should be written beside the error.
- You should insert your initials and date beside the correction, in some cases, it may be necessary to explain why you corrected the data (for example, if you changed a piece of data).

Records should always be filled in at the time the operation is performed. It is not good practice to "fill in the paperwork or enter the data afterwards".

It is also important that records are kept on the official form. Recording information on notepaper in order to fill in the official documents later is not acceptable as it could lead to transcription errors or omissions.

Appendix I - Table of Frequently Issued Product Codes
(Please refer to current Product Master File for comprehensive list)

Product Code	Text on Tag	Text on Product Label
54481	RC LD in AS for NNU for first 5 days	Red Cells Leucodepleted in additive solution suitable for neonatal use for 5 days after date drawn
04333	Red cells in AS Leucodepleted CPD SAGM	Red Cells in Additive Solution Leucodepleted
04403	Red cells leucodepleted washed	Red Cells, Leucodepleted, Washed
04236	Red cells in AS leucodepleted NNU	Red Cells in Additive Solution Leucodepleted for Neonatal Use (Primary unit)
04464	Red Cells Leucodepleted CPDA1	Red Cells Leucodepleted (CPDA1)
12769	Platelets pooled leucocytes depleted	Platelets Pooled Leucodepleted
58238	Platelets apheresis LD NNU	Platelet Apheresis Leucodepleted for Neonatal Use
10369	Cryoprecipitate Pooled, Frozen	Cryoprecipitate Pooled, Frozen
80160	Cryoprecipitate for NNU	Cryoprecipitate for Neonatal Use
12030	Platelet apheresis leucocyte depleted	Platelets Apheresis Leucodepleted
58340	Platelets apheresis leucodepleted S1	Platelets Apheresis Leucodepleted Split 1
58341	Platelets apheresis leucodepleted S2	Platelets Apheresis Leucodepleted Split 2
58342	Platelets apheresis leucodepleted S3	Platelets Apheresis Leucodepleted Split 3
54288	Platelets Aph LD Extended Life	Platelets Apheresis Leucodepleted, Extended Life
54289	Platelet Aph LD Ext Life S1	Platelets Apheresis Leucodepleted, Extended Life Split 1
54290	Platelet Aph LD Ext Life S2	Platelets Apheresis Leucodepleted, Extended Life Split 2
58238	Platelets apheresis LD NNU	Platelets Apheresis Leucodepleted for Neonatal Use
58235	Platelets apheresis LD NNU S1	Platelets Apheresis Leucodepleted for Neonatal Use Split 1
58236	Platelets apheresis LD NNU S2	Platelets Apheresis Leucodepleted for Neonatal Use Split 2
58237	Platelets apheresis LD NNU S3	Platelets Apheresis Leucodepleted for Neonatal Use Split 3
54388	Platelet Aph Ext Life NNU	Platelets Apheresis Leucodepleted, Extended Life for Neonatal Use
54389	Platelet Aph Ext Life NNU S1	Platelets Apheresis Leucodepleted, Extended Life for Neonatal Use Split 1
54390	Platelet Aph Ext Life NNU S2	Platelets Apheresis Leucodepleted, Extended Life for Neonatal Use Split 2